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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,294	12/19/2001	Suzie Hwang Pun	038134-5006	9341
28120	7590	04/21/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/021,294

Applicant(s)

PUN ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-7, 11-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 and 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Election/Restrictions*

The claims under prosecution remain subject to an election of species requirement, as set forth previously. In Applicant's response, filed October 22, 2004, Applicant inquires as to the reason for the withdrawal of claims 20 and 21. As noted in the previous Office action, the set of complexing agent species has been expanded to the "guest" molecules set forth in claim 11 with a generic therapeutic agent. Claims 20 and 21 require a complexing agent comprising a "host" entity, but the complexing agents under consideration at this point in the prosecution are limited to ones comprising a "guest" entity. However, it is further noted that upon allowance of a composition requiring a particular set of complexing agents comprising a guest entity, Applicant has the option of further comprising a complexing agent comprising a host entity *in addition to* that allowed set of complexing agents comprising a guest entity.

Applicant's arguments, filed October 22, 2004, with respect to the art rejections of the claims have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new rejection is made, as set forth below.

Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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***Claim Rejections - 35 USC § 102***

Claims 5-7 and 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by WOLFF et al (US 6,740,643).

WOLFF discloses several compositions comprising a cyclodextrin-containing polymer, plasmid DNA and a complexing agent. Complexing agents include 1-adamantamine. See examples 5-11.

***Claim Rejections - 35 USC § 103***

Claims 5-7 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WOLFF et al (US 6,740,643).

WOLFF teaches as set forth above. The reference further teaches that a cyclodextrin-containing polymer in combination with an amphiphilic compound results in drug delivery system that may be employed generically for biologically active compounds, such as pharmaceuticals, peptides/proteins, viruses, etc. See col 17, lines 50-52 and col 18, lines 32-47. The reference does not exemplify any other biologically active compounds other than polynucleotides.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute any of the biologically active compounds recited in claim 6 because these agents were expressly suggested by the reference. One of ordinary skill would reasonably expect success in making such a substitution because the reference had taught that this drug delivery system is a general one for biologically active compounds.

***Double Patenting***

Claims 5-7 and 11-21 are again provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-20 (change of claim set is in view of amendment to copending claims) of copending Application No. 10/021,312, as set forth in a previous Office action.

Applicant has indicated a willingness to submit a terminal disclaimer, if necessary, upon notice of allowability. Applicant has also directed the examiner's attention to the rejections in the copending application. The rejections have been reviewed and considered.

***Allowable Subject Matter***

Allowable subject matter was indicated in a previous Office action. Upon further searching, the scope of allowable subject matter is expanded to include a composition comprising:

1. a CD-containing polymer;
2. a therapeutic agent; and
3. guest—PEG (optionally including branching and additional linkers)—functional group.

As noted previously, "therapeutic agent," "guest," and "functional group" are generic. The art of record teaches as set forth above. The art does not provide any motivation to prepare complexing agents having PEG linkers.

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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

*Leigh C. Maier*

Leigh C. Maier  
Patent Examiner  
April 18, 2005